

ASSEMBLY BILL

No. 573

Introduced by Assembly Member Chu

February 18, 2003

An act to add Part 8.5 (commencing with Section 114490) to Division 104 of the Health and Safety Code, relating to public health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 573, as introduced, Chu. Public health: traditional Asian medicine and herbal health products.

Under existing law, The State Department of Health Services generally regulates the safety, content, packaging, advertising, and use of various food and drug products.

This bill would establish the Traditional Asian Medicine Certification Program to be administered by the State Department of Health Services. The bill would require the department to establish a list, to be published annually, of traditional Asian medicines and the products used in their production. This bill would require the department to adopt certification standards for traditional Asian medicines, and either test, or designate a certifying organization to test, every traditional Asian medicine that is to be produced, sold, or imported into this state, to determine if certification is warranted. This bill would require that the department monitor the list and labels of traditional Asian medicine and the ingredients used in the production to prevent the use of endangered species of flora and fauna.

This bill would also require that a fee be assessed, as established by the department, as a condition for the receipt of certification, with the fee to be used to defray the cost of implementing the bill. Fees collected

under the bill would be deposited into the Traditional Asian Medicine Certification Program Fund created by the bill, the moneys in which would be continuously appropriated for purposes of the bill.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) It is essential that the state take action to establish an effective and economical certification program for traditional Asian medicines and herbal health products.

(b) The certification program for traditional Asian medicines and herbal health products is essential to protect the health and welfare of the people of the state from exposure to harmful levels of metals and other contaminants in traditional Asian medicines and herbal health products. Because of the high demand and easy access to traditional Asian medicines and herbal health products, it is extremely important for the safety of all consumers that a maximum permitted standard of concentration of metals and contaminants be established for traditional Asian medicines and herbal health products produced, sold, or imported into California.

SEC. 2. Part 8.5 (commencing with Section 114490) is added to Division 104 of the Health and Safety Code, to read:

PART 8.5. TRADITIONAL ASIAN MEDICINE
CERTIFICATION PROGRAM

CHAPTER 1. DEFINITIONS

114490. For purposes of this chapter, the following definitions shall apply:

(a) “Allowable contaminants” means, with respect to food standards, the standards established by the State Department of Health Services that establish the maximum permitted concentrations of metals and contaminants in foods based on a milligram of metal or contaminant per kilogram of food measurement.

(b) “Department” means the State Department of Health Services.

(c) “Program” means the Traditional Asian Medicine Certification Program established by this part.

(d) “Traditional Asian medicine and herbal health products” means the treatments and practices of protecting and restoring health that existed in Asia before the arrival of modern Western medicine. These health care treatments and practices belong to the traditions, which have been handed down from generation to generation, of utilizing local natural resources of plants, animals, and minerals. Traditional Asian medicine, in particular, is a very sophisticated set of systems based on the practice of herbal medicine, utilizing both plants and animals, that has become commercialized and exported as an alternative to western medicine throughout the world.

CHAPTER 2. CERTIFICATION PROGRAM

114491. (a) The State Department of Health Services shall establish and administer a comprehensive statewide Traditional Asian Medicine Certification Program.

(b) The department shall develop and implement the program in cooperation with traditional Asian medicine vendors and herbal health product companies.

114492. The department shall, in consultation with professionals, establish a list of traditional Asian medicines and products used in the production of traditional Asian medicines, based on a survey of literature and pharmacopoeia. The department shall publish the list of traditional Asian medicines and products used in their production on an annual basis.

114493. (a) Traditional Asian medicines and herbal health products produced, sold, and imported into this state that are voluntarily submitted for certification shall be tested and monitored by the department, or a certifying organization designated by the department, to determine whether certification is warranted.

(b) The department shall adopt certification standards for the program. These standards shall be based upon both of the following:

1 (1) Any regulations adopted by the traditional Asian medicine
2 and herbal health product companies pursuant to a self-regulatory
3 program that is consistent with applicable state and federal law,
4 and international agreements.

5 (2) Existing international standards for allowable limits of
6 contaminants and any additional, more restrictive standards for
7 allowable limits of contaminants adopted by the department, to the
8 extent permissible under any applicable treaties.

9 114494. (a) Traditional Asian medicines and herbal health
10 products submitted to the department for certification shall be
11 monitored for the use of endangered flora and fauna, including any
12 ingredients thereof, listed under the federal Endangered Species
13 Act (16 U.S.C. Sec. 1531 et seq.), the California Endangered
14 Species Act (Chapter 1.5 (commencing with Section 2050) of
15 Division 3 of the Fish and Game Code), and the endangered
16 species listed in Appendix I of the Convention on International
17 Trade and Endangered Species of Wild Fauna and Flora (CITES)
18 in the production of any traditional Asian medicines and herbal
19 health products.

20 (b) No medicine or herbal health product shall be certified
21 under this part if its use is prohibited by any of the laws or treaties
22 set forth in subdivision (a).

23 114495. Traditional Asian medicines and herbal health
24 products submitted to the department shall be monitored and
25 inspected to ensure that any product containing flora and fauna has
26 been properly imported and labeled with respect to state and
27 federal law and CITES' requirements.

28 114496. (a) A traditional Asian medicine or herbal health
29 product shall not be certified until the certification fee required by
30 this section has been paid.

31 (b) The department shall establish the amount of the
32 certification fee due under this section. The amount of the fee shall
33 not exceed a reasonable amount as necessary for administration of
34 this part. The fees charged pursuant to this section shall be
35 sufficient to defray the costs of implementing this part.

36 (c) The certification fee required by this section shall be due
37 and payable on or before the 10th day of the month following the
38 month in which the decision to grant the certification is issued.
39 Any person who does not pay the amount due within the required

1 time shall, in order to receive certification, pay an additional
2 penalty of 10 percent of the total amount determined to be due.

3 114497. (a) The department shall ensure that a certificate
4 issued under this part states the true quality and condition of the
5 medicine or product being certified.

6 (b) The department shall furnish a copy of the certificate to the
7 party requesting the certificate, upon receipt of the certification fee
8 required by this part.

9 (c) The department shall keep a copy of the certificate on file.

10 (d) The department shall provide any interested party, upon
11 written or oral request, with a copy of the certificate.

12 114498. The department shall cooperate with other
13 competent state and federal agencies, organized herbal task forces,
14 and other recognized international organizations whose primary
15 goal is to ensure the protection of public health, in the pursuit of
16 seeking compliance with state and federal law, and international
17 agreements.

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19 CHAPTER 3. CERTIFICATION ORGANIZATIONS
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21 114499. (a) The department may designate private for-profit
22 or nonprofit entities, including laboratories, to perform testing or
23 inspections for the program.

24 (b) In order to be designated pursuant to subdivision (a), the
25 entity, and any employee of the entity concerned with certification
26 of traditional Asian medicines and herbal health products, may not
27 have any financial interest in the production, processing, or sale of
28 any traditional Asian medicine and herbal health products.

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30 CHAPTER 4. FISCAL PROVISIONS
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32 114500. (a) There is hereby created in the State Treasury the
33 Traditional Asian Medicine Certification Program Fund, which,
34 notwithstanding Section 13340 of the Government Code, is
35 continuously appropriated without regard to fiscal years for the
36 purpose of implementing this part.

37 (b) The department shall deposit all fees received pursuant to
38 Section 114496 into the fund. In addition to fees, the fund shall
39 consist of any federal funds that may be received for purposes of
40 this part, private gifts or grants which may be procured by the

1 department for purposes of this part, and any interest earned on
2 money contained in the fund.

3 114501. (a) It is the intent of the Legislature that funds be
4 appropriated in the Budget Act, in an amount not to exceed two
5 hundred fifty thousand dollars (\$250,000), to defray the startup
6 costs for the implementation of this part. This appropriation, plus
7 interest, shall be repaid within a reasonable period of time.

8 (b) For purposes of this section, startup costs shall include
9 initial salaries of personnel, the costs of facilities and services for
10 which the department contracts, including costs incurred by
11 certifying organizations, and other costs incurred by the
12 department in implementing this part.

13 (c) Upon the receipt of funds from public or private sources for
14 use in the certification program established pursuant to this part,
15 the department shall determine the amount of funds available for
16 allocation to any other related certification programs.

